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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/076,448 | 02/19/2002 | Junko Kudo | Q68586 | 9880 |

7590 07/18/2003

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| EXAMINER |
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BERNHARDT, EMILY B

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| ART UNIT | PAPER NUMBER |
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1624

DATE MAILED: 07/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/076,448

Applicant(s)

KUDO et al.

Examiner

Emily Bernhardt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/2/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above, claim(s) 5-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 6) ☐ Other:

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Applicant's election of I in Paper No.8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 10 and 11 were inadvertently omitted in the groups but belong to group II as they depend on claim 9. It has been so corrected in the PTO's copy.

The abstract of the disclosure is objected to because it does not set forth an intended use. Correction is required. See MPEP § 608.01(b).

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. In claim 13 symbols X and * are indicated as "defined above" but they are not defined in this claim. As 13 is an independent claim it must completely define all recited variables.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2 and 3 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Weston (US'269).

Weston describes a narrow genus of piperazine esters (i.e. C1-C4 alkoxy) for use as synthetic precursors to compounds exhibiting antihistaminic activity. See formula in claim 1 directed to the carboethoxy esters along with specific decarboxylated species such as eg. IV. The list of 8 possible esters covered by the C1-C4 alkoxy range coupled with the decarboxylated species that is taught is formed therefrom constitutes an anticipation of the instant t-butyl ester when X=Cl in view of the narrow genus present. See *In re Petering* 133 USPQ 275; *In re Schaumann* 197 USPQ 5; *In re Sivaramakrishnan* 213 USPQ 441 regarding anticipation requirements.

If the genus is deemed too large to place the instant t-butyl ester described above in the public's possession, it is otherwise an obvious variant in view of the

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generic teaching to employ C1-C4 alkyl esters as set forth in claim 1. Thus it would have been obvious to one skilled in the art at the time the invention was made to employ aforementioned t-butyl ester for use as a chemical intermediate for making decarboxylated species in view of the equivalency teaching outlined above.

Claims 1,4 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weston in view of Cossement (US'941). The teachings of Weston as discussed in the above 102/103 rejections is incorporated herein. Claims rejected herein are directed to optically active esters and their use as reactant to making decarboxylated species. While Weston does not employ his esters in optically active form, Cossement teaches that acylated piperazines that have the same chlorobenzhydryl group on the other piperazine terminus as Weston are useful in their enantiomeric form for providing optically active "deacylated" intermediate product of formula IV. See formula (I) compound in col.1 which is tosylated. Formula (IV) in Cossement corresponds to racemic eg. IV in Weston. Said compounds are then further derivatized to yield final products of formula V in Cossement which also include the same final product taught in Weston (see col. 2 where R1=methyl). Given the need to resolve said final products for use in their optically pure form, it

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would have been obvious to one skilled in the art at the time the instant invention was made to also resolve the acylated piperazine (i.e. esters) of Weston in the manner taught for sulfonyl derived piperazine in Cossement (see col.3) with the expectation of providing additional optically active intermediates for the same or similar final products taught in both of the references. Note that Weston teaches the decarboxylation process of claim 13 with esters as the free base or in salt form followed by treatment with acid or base. See col.1, last paragraph and example III. One would expect the same result from the optically active precursor given the asymmetric site is not the reaction site.

Any inquiry concerning this communication should be directed to Emily Bernhardt at telephone number (703) 308-4714.

A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.

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F Bernhardt
EMILY BERNHARDT

PRIMARY EXAMINER

GROUP 1600